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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,984	07/21/2004	Adreas F. Schaub	2923-763	3383

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EXAMINER

HOFFER, SUSANNA MARIE

ART UNIT	PAPER NUMBER
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1609

NOTIFICATION DATE	DELIVERY MODE
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07/12/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary

Application No.

10/501,984

Applicant(s)

SCHAUB, ADREAS F.

Examiner

Susanna Hoffer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :July 21, 2004 and Oct. 31, 2006.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12, 13, 15-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Leuven (US 4,267,168).

Claim 12 recites a method for easing vaginal child birthing in a woman, which comprises introducing a composition comprising a physiologically acceptable organic lubricant and no alkali metal salts of metaphosphates in an effective amount into the birth canal. Van Leuven teaches a composition useful for treating herpes virus, condyloma, and for preventing Staphylococcus aureus infection and a method in which the composition is applied to the vaginal tissue of a baby's mother as a lubricant and thereafter delivering the baby (col. 6, lines 52-55 and claim 12). This composition does not contain any alkali metal salts of metaphosphates.

Claims 13 and 15 recite the method of claim 12, wherein an organic substance itself brings about a lubricant effect in the composition, or in that the organic substance confers a lubricant effect through formulation of the composition. Wherein the organic substance brings about a lubricant effect, it comprises soluble, emulsifiable, dispersible, optionally low molecular weight, optionally biodegradable and/or optionally bioadhesive

organic oligomer or polymer formulated as a composition optionally forming a lubricant film or acting as a lubricant. Van Leuven teaches a composition comprising glycerine, an organic lubricating substance that is also soluble (col. 5, lines 58-62).

Claim 16 recites the method as claimed in claim 13, wherein the organic substance which confers a lubricant effect through formulation of the composition comprises a polymer which can be swelled by an organic solvent and/or water and which form a gel. Van Leuven teaches a composition comprising sodium polypectate, which provides a viscosity suitable for a variety of purposes including assist during delivery and which can gel the composition at a pH less than 7 (col. 3, lines 64-69 and col. 6, lines 15-16).

Claims 17 and 18 recite the method of claim 12, wherein the composition is in the form of a liquid, paste, gel, cream, suppository, solution, emulsion, dispersion, oil or hydrogel. Van Leuven teaches a lubricating composition in the form of a liquid solution or a gel (col. 6, lines 15-16).

Claims 19-21 recite the method of claim 12, wherein the organic lubricant is present in an amount from 1-99% and wherein the composition further comprises one or more pharmaceutically active ingredients in an amount from 0.0001 to 10% by weight. Van Leuven teaches a composition containing glycerin, an organic lubricant, in an amount from 4 to 10% by weight and sodium polypectate and silver ion, the pharmaceutically active ingredients, in ranges from 100 to 400 and 13 to 30 parts per million respectively (col. 16, lines 7-25).

Claim 22 recites the method as claimed in claim 20, wherein the active pharmaceutical ingredient serves to inhibit child birthing or promote child birthing, alleviate pain, prevent infection or prevent neonatal respiratory distress syndrome. Van Leuven teaches a method of preventing bacterial infection on human tissue using liquid biocidal compositions (col. 15, lines 19-31).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Leuven (US 4,267,168) in view of Levy (US 2001/0014711).

Claim 14 recites the method as claimed in claim 13, wherein the organic substance with a lubricant effect comprises a natural or synthetic oil, fat or wax. Levy teaches a lubricant comprising petroleum, water, grease, synthetic lubricant, or solid lubricant (see abstract). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a lubricant with any of these characteristics because they are well known in the field of lubricants.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susanna Hoffer whose telephone number is (571)272-

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9345. The examiner can normally be reached on Monday - Friday, 9:00 a.m.-5:00 p.m., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571)272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SMH



JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER